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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,512	03/12/2004	Steven M. Ruben	PZ039P1C2	6667

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EXAMINER
JIANG, DONG

ART UNIT	PAPER NUMBER
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,512	RUBEN ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, claims 1-24 are under pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 14, 15, and 21, drawn to an isolated nucleic acid molecule, a vector containing same, a host cell thereof, and a method of recombinantly producing the encoded polypeptide, classified in class 435, subclass 69.1.

II. Claims 11, 12, and 16, drawn to an isolated polypeptide, classified in class 530, subclass 350.

III. Claim 13, drawn to an isolated antibody, classified in class 530, subclass 387.9.

IV. Claim 17, drawn to a method for preventing, treating, or ameliorating a medical condition with the polynucleotide, classified in class 514, subclass 44.

V. Claim 18, drawn to a method of diagnosing a pathological condition by determining a mutation in the polynucleotide, classification depending upon the method steps.

VI. Claim 19, drawn to a method of diagnosing a pathological condition by determining the expression levels of the polypeptide, classification depending upon the method steps.

VII. Claim 20, drawn to a method for identifying a binding partner to the polypeptide, classified in class 436, subclass 501.

VIII. Claim 22, drawn to a method of identifying an activity in a biological assay, classified in class 435, subclass 4.

IX. Claim 23, drawn to a binding partner, classification depending upon the chemical entity made.

X. Claim 24, drawn to a method for preventing, treating, or ameliorating a medical condition with the polypeptide, classified in class 514, subclass 2.

The inventions are distinct, each from the other because:

The nucleic acid of Invention I is related to the polypeptide of Invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecules and proteins are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The method of Invention I is related to the polypeptide of Invention II as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the product as claimed may be isolated from their natural source or made by chemical peptide synthesis.

The nucleic acid of Invention I is distinct and unrelated from the antibody of Invention III because they are physically and functionally distinct chemical entities which share neither structure nor function. The method of Invention I is distinct and unrelated from the antibody of Invention III because the antibody may be neither made by nor used in the method.

Invention I is related to Inventions IV and V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the production of the polypeptide of Invention II.

Invention I is distinct from and unrelated to Inventions VI-VIII, and X, wherein the products of Invention I can be neither made by nor used in the methods of Inventions VI-VIII, and X, and wherein each does not require the other.

The products of Invention I are distinct and unrelated from the binding partner of Invention IX because they are physically and functionally distinct chemical entities which share neither structure nor function. The method of Invention I is distinct and unrelated from the

binding partner of Invention IX because the binding partner may be neither made by nor used in the method.

The polypeptide of Invention II is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

Invention II is distinct from and unrelated to Inventions IV and V, wherein the product of Invention II can be neither made by nor used in the methods of Inventions V and VI, and wherein each does not require the other.

Invention II is related to Inventions VI-VIII and X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the production of the antibody of Invention III.

The product of Invention II is distinct from and unrelated to the binding partner of Invention IX because they are physically and functionally distinct chemical entities which share neither structure nor function.

Invention III is distinct from and unrelated to Inventions IV-VIII and X, wherein the antibody of Invention III can be neither made by nor used in the methods of Inventions IV-VIII and X, and wherein each does not require the other.

The antibody of Invention III is distinct from and unrelated to the binding partner of Invention IX because they are physically and functionally distinct chemical entities which share neither structure nor function.

Inventions IV-VIII and X are drawn to various independent methods, wherein each of the methods is distinct and unrelated to the other methods, each not requiring the other, as each has

different process steps, different active agents, and different starting and ending points, such that they require separate searches.

Invention IX is distinct from and unrelated to Inventions IV-VIII and X, wherein the product of Invention IX can be neither made by nor used in the methods of Inventions IV-VIII and X, and wherein each does not require the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

2. Furthermore, if applicants elect any one of the groups set forth above, further **restriction** is required under 35 U.S.C. 121:

A. Elect one specific nucleotide sequence for "X" with a SEQ ID NO from Table 1, and/or

B. Elect one specific amino acid sequence for "Y" with a SEQ ID NO from Table 1.

The inventions are distinct, each from the other because of the following reasons:

Table 1 of the specification lists 86 nucleotide sequences and 86 amino acid sequences encoded thereby. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of the invention from Groups I-X, and an election of the invention from Group A or B, to be examined even though the requirement be traversed (37 CFR 1.143),

and (ii) identification of the claims encompassing the elected invention. Applicant is advised that neither I-X nor A and B is species election requirement; rather, each of I-X, A and B is a restriction requirement.

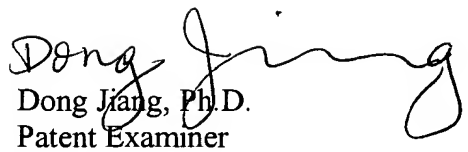
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dong Jiang, Ph.D.
Patent Examiner
AU1646
12/16/06